General

Guideline Title

Special considerations in pregnancy. In: British HIV Association and British Infection Association guidelines for the treatment of opportunistic infection in HIV-seropositive individuals 2011.

Bibliographic Source(s)

Greig JM, Wood CGA, Clarke SU. Special considerations in pregnancy. In: British HIV Association and British Infection Association guidelines for the treatment of opportunistic infection in HIV-seropositive individuals 2011. HIV Med. 2011 Sep;12(Suppl 2):102-8. [67 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Level of evidence (I–IV) ratings are defined at the end of the "Major Recommendations" field.

Background and Epidemiology

- Opportunistic infections in human immunodeficiency virus (HIV)-seropositive pregnant women should be managed with close collaboration between HIV specialists, obstetricians, paediatricians and where possible, specialists in obstetric medicine and materno–foetal medicine (IV).
- Therapeutic drug monitoring (TDM) should always be considered due to altered drug pharmacokinetics in pregnancy, and the potential for complicated multiple interactions between antiretrovirals and many of the drugs used to treat opportunistic infections (Kaplan et al., 2009; Back, Gibbons, & Khoo, 2006).

Diagnostic Considerations in HIV-seropositive Pregnant Women

Radiology

- When choosing imaging modality for the diagnosis of opportunistic infections in pregnant women consideration should be given to the need for a rapid diagnosis and the potential harm of the investigation. Discussion between HIV specialists, obstetricians and senior radiologist is recommended (IV).

Diagnostic Considerations for the Foetus and Newborn Baby

Vertical Transmission of Maternal Opportunistic Infections to the Neonate

- Neonates born to HIV-seropositive women should be assessed by a paediatrician, and where necessary actively screened, for congenital opportunistic infections. The placenta should also be examined histologically for signs of infection or disease (IV).

Refer to the original guideline document for treatment considerations for other specific opportunistic infections during pregnancy.

Definitions:

Level of Evidence

Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well designed controlled study without randomization
IIb	Evidence obtained from at least one other type of well designed quasi-experimental study
III	Evidence obtained from well designed non-experimental descriptive studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Opportunistic infections
- Pregnancy
- Human immunodeficiency virus (HIV) seropositivity

Guideline Category

Diagnosis

Evaluation

Management

Prevention

Screening

Treatment

Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Pediatrics

Pharmacology

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Pharmacists

Physician Assistants

Physicians

Guideline Objective(s)

To help physicians in the United Kingdom investigate and manage human immunodeficiency virus (HIV)-seropositive pregnant patients suspected of or having an opportunistic infection

Target Population

Human immunodeficiency virus (HIV)-seropositive, pregnant patients suspected of or having an opportunistic infection and their foetuses and newborn infants

Interventions and Practices Considered

1. Close collaboration between human immunodeficiency virus (HIV) specialists, obstetricians, paediatricians, and specialists in obstetric medicine and materno–foetal medicine
2. Therapeutic drug monitoring (TDM)
3. Safety considerations for choice of imaging modalities during pregnancy (x-rays, computed tomography [CT], magnetic resonance imaging [MRI], and use of contrast)
4. Screening newborns for congenital opportunistic infections
5. Treatment considerations for specific opportunistic infections

Major Outcomes Considered

- Morbidity and mortality (maternal and fetal)
- Adverse events related to therapy and drug interactions
- Vertical transmission of maternal opportunistic infection to the neonate (congenital infection)
- Teratogenic effects of drugs
- Risk of birth defects
- Effectiveness of drug treatments

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

All information considered had to have been published in a peer review journal or presented at an international human immunodeficiency virus (HIV) meeting in abstract form. Inclusion/exclusion criteria essentially required that the information was relevant to the diagnosis, treatment or prevention of the specified opportunistic infection in HIV-positive individuals. Information of relevance to other related immunocompromised groups was also taken into consideration if the section authors felt relevant. Case reports were included and the review was not restricted only to clinical trials or meta-analyses. Search dates were from 1980 to January 2011.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Level of Evidence

Ia	Evidence obtained from meta-analysis of randomized controlled trials
Ib	Evidence obtained from at least one randomized controlled trial
IIa	Evidence obtained from at least one well designed controlled study without randomization
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III	Evidence obtained from well designed non-experimental descriptive studies
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Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Not stated

Description of Method of Guideline Validation

Not applicable

Evidence Supporting the Recommendations

References Supporting the Recommendations

Back D, Gibbons S, Khoo S. An update on therapeutic drug monitoring for antiretroviral drugs. Ther Drug Monit. 2006 Jun;28(3):468-73. PubMed

Kaplan JE, Benson C, Holmes KH, Brooks JT, Pau A, Masur H, Centers for Disease Control and Prevention (CDC), National Institutes of Health, HIV Medicine Association of the Infectious Diseases Society of America. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. MMWR Recomm Rep. 2009 Apr 10;58(RR-4):1-207; quiz CE1-4. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for most recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate treatment of opportunistic infections in pregnant, human immunodeficiency virus (HIV)-seropositive individuals

Potential Harms

- Where an opportunistic infection is being treated, the foetus should be closely monitored, for example by serial high-resolution ultrasound scans and foetal cardiac monitoring, so that signs of disease, growth retardation, foetal distress or possible drug toxicity in the foetus can be detected early.
- Refer to section 11.4 in the original guideline document, "Treatment considerations for specific opportunistic infections," for a discussion of safety concerns for drugs used during pregnancy. Also refer to Appendix 1 in the original guideline document for side effects of certain drug formulations.

Contraindications

Contraindications

- Plain abdominal X-rays should generally be avoided during pregnancy.
- A direct computed tomography (CT) scan of the foetus in the pregnant abdomen is contraindicated and, where possible, should be avoided. Magnetic resonance imaging (MRI) scanning of the foetus and abdomen may be considered, although it is recommended to avoid them in the first trimester unless absolutely necessary.
- Gadolinium, which is used in MRI scanning, is not recommended as it has been found to be teratogenic in some animal studies, and should be avoided if possible.
- Refer to section 11.4 in the original guideline document, "Treatment considerations for specific opportunistic infections," for a discussion of safety concerns for drugs used during pregnancy, many of which should be avoided in the first trimester of pregnancy.
- Refer to Appendix 1 in the original guideline document for contraindications of certain drug formulations.

Qualifying Statements

Qualifying Statements

- These guidelines are primarily intended to guide practice in the United Kingdom and related health systems. Although it is hoped they can provide some guidance in developed countries there are some important distinctions in this environment and individual recommendations may not be as applicable in this setting.
- In the appendices in the original guideline document there is an A–Z of drugs used in the management of opportunistic infections. This is intended as a guideline but readers are advised to follow the discussion of dosing and the evidence for specific treatments provided in the text. In some cases alternative treatments are provided in the appendix in the original guideline document. These are not discussed in the text and these are mainly of historical interest and readers should be aware that these are not, in general, supported by the evidence base for treatments discussed in the text. It should also be noted that as evidence of drug toxicity, interactions, pregnancy risk and cost is rapidly evolving the table should be considered in association with the updated summary of product characteristics (SPC) for the agent and other relevant sources of drug information.
- Recommendations based upon expert opinion have the least evidence but perhaps provide an important reason for writing the guidelines: to produce a consensual opinion about current practice. It must, however, be appreciated that such opinion is not always correct and alternative practices may be equally valid. The recommendations contained in these guidelines should therefore be viewed as guidelines in the true spirit of the term. They are not designed to be restrictive nor should they challenge research into current practice. Similarly, although the British HIV Association (BHIVA) Opportunistic Infection Guidelines Group seeks to provide guidelines to optimize treatment, such care needs to be individualized and the authors have not constructed a document that they would wish to see used as a 'standard' for litigation.
- The clinical care of patients with known or suspected opportunistic infections (OIs) requires a multidisciplinary approach, drawing on the skills and experience of all healthcare professional groups. Moreover, these guidelines emphasize that inpatients with human immunodeficiency virus (HIV)-related disease often need rapid access to a variety of diagnostic tests and radiological interventions that may not be immediately available at local hospitals. Furthermore, expert interpretation of these tests by supporting specialties such as radiology, histopathology, microbiology and virology is often required. Optimal care of opportunistic infection can only be achieved by the close cooperation of these healthcare professionals and unless all are intimately involved in the care of patients, it is likely that the outcome will be less favourable. In keeping with BHIVA standards for HIV clinical care, patients needing inpatient care for HIV-related disease should ordinarily be admitted to an HIV centre or the relevant tertiary service in liaison with the HIV centre.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Mobile Device Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Sep

Guideline Developer(s)

British HIV Association - Disease Specific Society

British Infection Association - Professional Association

Source(s) of Funding

British HIV Association

Guideline Committee

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Financial Disclosures/Conflicts of Interest

The British HIV Association (BHIVA) has a clear policy of declarations of interests within the Association:

- BHIVA requires that all members of guidelines writing groups, as well as any expert external peer reviewers, must declare all interests and membership of other committees retrospectively on an annual basis, to give protection to individuals working as members of writing groups.
- All members of guidelines writing groups must undertake a declaration of interests prior to serving on a writing group and this declaration is confirmed and repeated at the publication of each set of completed guidelines published.
- The details given in declaration forms are retained on a register at the Secretariat and can be made available for publication, if required.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the British HIV Association (BHIVA) Web site . Also available as a smartphone app from the BHIVA Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

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